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Medtronic Attn: Noreen C. Johnson, IP Legal Department 2600 Sofamor Danek Drive Memphis, TN 38132			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/773,815	Applicant(s) EISERMANN ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-21 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-21 and 31-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/10/09, 10/13/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

Applicant should note that the large number of references in the attached IDS submittals have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b)**. Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action. Note there was a duplicate submission of some pages of the IDS submitted on 7/10/09

Response to Arguments

Applicant's arguments filed 9/28/09 have been fully considered but they are not persuasive. Applicants' first argument addresses the drawing objection and states the claimed limitations are shown in the different embodiments, but fails to state where a vertebral body can be shown that has the claimed sidewalls with slots in it to receive the keels of the intervertebral implant while also having bone screws inserted in the same walls. The Examiner is not persuaded and the objection is maintained because the specific locations of such insertion members that engage the vertebra can interfere with the slots and is not evident by the separate embodiments since they are described as alternatives and not a combination.

Applicants argue that the specification need not contain limitations of claims precisely as presented in the disclosure but only that the limitations are basically understood. The Examiner agrees, however, in a method of using apparatus to correct disorders or injuries, it is critical to describe how to use such apparatus with precision, not without support. After further review and since Applicants cannot provide support it is clear that the limitation of the insertion member or screws specifically to not engage the pedicle or be spaced from it is new matter and is rejected and presented below.

In response to Applicants arguments on the 112 1st paragraph rejection of claims 14-16 and 31-39 with respect to using the combination of features of a rod and screws with an intervertebral implant that has a keel to be placed in slots of the vertebral walls. While the Examiner agrees there is support for the individual embodiments, it is clear that the intervertebral embodiment is mentioned as an alternative to using a rod and screws. The Applicants did not refer to any paragraph stating that the rod and screws are used with the intervertebral implant or is there any recitation that the rod and screws are removed or left in place or in a position that enables insertion of the intervertebral implant which has been placed. The intervertebral implant with keels of Applicants invention are shown with a ball and socket formation to allow for movement of the vertebrae by rotation just as the rod and screw arrangement permits. Therefore it is not clear how any such combination works together when they are presented as alternative methods to adjust for spondylolisthesis.

Applicants argue that the method of repairing the spine disclosed by Laurain is not for spondylolisthesis. However, first it must be noted that in interpreting claims the

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preamble begins to set forth the metes and bounds of the scope sought for protection.

The body of the claim often supports the preamble and thus the claim can be said to be clear. However, when the preamble is not further limited in the body of the claim from a recitation of an intended use recited in the preamble, it is not clear that the preamble is actually limiting. In this case, the body of the claims (12, 31) state the vertebrae are in a spondylosed relationship. In reviewing the medical dictionary titled Mosby's, the term or prefix "spondylo-" means vertebra or spinal column. Thus, the claims do not set forth any particular spinal disorder relationship but that the vertebrae are oriented in some way possibly incorrectly. Therefore, in applying the Laurain reference, it is clear that a disorder described by Laurain (col. 1) has caused spinal vertebrae misalignment as defined and can be considered a "spondylosed relationship". It can thus be said that the preamble is not limiting and the claims lack the specific step (see 112 2nd below) of diagnosing the specific disorder of spondylolisthesis as recited in the preamble only.

In response to Applicants arguments that Laurain is alleged to be performed by another nominal approach, it is noted that the insertion members are placed in a direction to the walls of the vertebrae that is transverse to their main axis and thus can be said to be laterally inserted.

In response to applicant's arguments against the Jackson, Conchy and Kapp references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Most importantly, Conchy teaches the sidewall lateral

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insertion not in a pedicle and can be said to just be an obvious expedient to the procedure of Jackson's method. Second Applicants have misunderstood the rejection presented over Jackson modified with Conchy and Kapp in that Jackson, regardless of the planes through the body, the insertion member clearly goes through the sidewall and is thus laterally inserted. It cannot be considered to be inserted from the top, bottom or an angle, but only through a lateral side approach.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the lateral walls that have received screws for a connection rod and also have slots prepared for a intervertebral prosthesis must be shown or the feature(s) canceled from the claim(s). The drawings are noted by the Examiner to show the features separately, but not one drawing was said to be described to illustrate the claimed combination. The Examiner notes the claims had recited the connection rod was removed and the claims now do not include such a recitation thus, if the claimed combination is possible with the apparatus as claimed it must be shown. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

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number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the recitations that the laterally inserted screws (insertion members) areand not engaging a pedicle of the vertebrae or spaced from the pedicle was not found in the written disclosure. Because the spinal vertebrae consists of numerous anatomical portions, it is critical to describe how apparatus for repairing or correcting spinal disorders or injuries is inserted and where.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-21,31-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 12 recites that the insertion members are inserted laterally "to not engage the pedicle of the vertebrae" which is not described in the specification and is new matter. Additionally, claim 31 recites that the insertion members are inserted laterally "to be spaced from the pedicle of the vertebrae" which is not described in the specification and is also new matter. The vertebrae consist of numerous bone portions that is capable of receiving the insertion members or screws. These bone portions include the vertebral body, pedicles, the lamina and an arch that supports facet joints. Therefore, it is critical to establish, especially in a method of using apparatus to repair bones, as to where exactly it is placed. The written disclosure fails to describe such positioning of the insertion members in the vertebrae and to exclude placement with respect to the pedicle is new matter.

Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The preparation of a vertebral lateral wall to have slots formed therein that has insertion members (screws) placed in the same lateral walls such that the walls are not compromised is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re*

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Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The Examiner notes the recited references by the Applicant to specific drawings (Figs. 2,3a,3b,7,8,10,19) and the written description of paragraphs 72-119. However, the Examiner fails to see where any of the recited disclosure describe a vertebrae designed to receive such a combination of the two corrective apparatus features inserted in the vertebrae and any particular drawing illustrating a lateral wall that has both corrective apparatus in combination together. What the Examiner has reviewed by the Applicant all describe individual apparatus intended to be used in separate methods of corrective repair, not in combination.

Claims 31-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure does not describe the method of correcting spondylolisthesis as including the use of lateral screws and an elongate member or rod *in combination* with insertion of an implant **between** the vertebrae. How is this possible? If the lateral slots are formed for the implant, there is no safe area in the lateral sidewall then to receive the bone screws for the elongate rod or vice versa. The claims recite both apparatus (implant and correction rod system) are inserted or used laterally, thus it is not possible to perform this with both sets of apparatus used laterally as claimed in claim 36. Regarding claim 37, the disclosure describes the

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insertion of the apparatus described above, but fails to describe removal of the apparatus.

Claims 12-21,31-39 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: evaluating a patient and determining that the patient has spondylolisthesis. A spondylosed relationship may be defined by an incorrect curvature, however, it is a broad description and cannot be said to be limited to spondylolisthesis. The prefix "spondylo" means vertebra or the spinal column as defined by Mosby's medical dictionary. Thus, since the body of the claims (12,31) do not further establish the method has a step for diagnosing the spinal vertebral disorder, it can be said that the preamble does not limit the body of the claim to correcting the specific "intended degenerative spinal disorder" as claimed.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12,13,17,21,31-35,38 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Laurain (5108395). Laurain discloses a method for correcting a spinal condition having incorrect curvature by removing an intervertebral disc, col. 1, lines 25-30, col. 6, lines 49-52. The surgeon then inserts laterally into the sidewall of the vertebrae, clamps and bone screws, (Figs. 1,9) and then a connecting member **6** is joined to engage the clamps to

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span between the vertebrae. Note that since insertion members are inserted into the walls of the vertebrae in a direction transverse to the axis of the vertebrae, it can be considered to be laterally inserted. Laurain discloses that a rotating force is applied to the connecting member to rotate the vertebrae relative to one another, col. 3, lines 4-16, col. 7, lines 18-21, 47-52. The Examiner interprets a “spondylosed relationship” as a incorrectly curved spine. With respect to claim 13, the examiner is interpreting the claimed elements “prosthetic joint” in this way: an object between the vertebrae in the “joint” space. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054, 1055. Thus, since Laurain illustrates (Fig. 8,9) a prosthetic graft **G** in the joint space, it can be considered a “prosthetic joint”. Regarding claim 21, it is inherent that the surgeon uses a wrench to rotate the screws having hex head sections. A surgeon cannot use his hands to do this. With respect to claim 33, it is known in the art that grafts promote fusion. Regarding claim 34, it is inherent that the graft will permit some articulation or motion (which can be compression) between the vertebrae. Since placement of the elongate member **6** is on the lateral side of the vertebrae, it can be considered a lateral approach. However, in the alternative, Laurain fails to explicitly state the method corrects spondylolisthesis. Since Laurain discloses correcting an incorrectly curved spine, it would have been obvious to one of ordinary skill in the art to use the method of Laurain in correcting a patient with spondylolisthesis since it would involve adjusting an incorrect curvature and the results would be predictable in moving the vertebrae in a more straight alignment.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laurain '395. Laurain is explained supra. However, Laurain fails to disclose the implant is inserted laterally. It would have been obvious to one of ordinary skill in the art to insert the implant while performing the surgery in the patient to place the implant laterally into the patient before placing the elongate member onto the screws since this would not require any more incisions in the patient since the lateral side has been exposed. It is common sense that a surgeon would minimize the incisions a patient would require such that the healing is kept to a minimum.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laurain '395 in view of Jacobson et al. (5382248) and Conchy et al. (6749612). Laurain is explained supra. However, Laurain fails to disclose disengaging the elongated member from the insertion members and removing it along with the insertion members from the sidewall of the vertebrae. Conchy et al. teach (Fig. 8) that rods **2,3** spanning between vertebrae can be removed, col. 6, lines 28-30. Jacobson et al. teach that bone screws can become loose and broken to require removal, col. 6, lines 16-26, col. 12, lines 11,12,35-45. It would have been obvious to one of ordinary skill in the art to remove an incorrect elongate member as taught by Conchy et al. and broken screws as taught by

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Jacobson et al. from the vertebrae inserted by the method of Laurain such that problems with the correction apparatus can be corrected if necessary.

Claims 12,13,17,20,21,31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (5591165) in view of Conchy et al. (6749612) and Kapp et al. (4554914). Jackson discloses (Figs. 9A-C) a spondylolisthesis correction system including bone screws laterally inserted into first and second lateral sidewalls of the vertebrae and a connecting member or rod **1** is spanned between the vertebrae. Jackson also discloses the connecting member is rotated (Fig. 9B) and discloses the system is used to correct spinal deformities by rotation from a lateral approach since it placement of the vertebral insertion members engage side walls of the vertebrae, col. 10, lines 6-10,19-41. However, Jackson fails to disclose that the insertion members do not engage pedicles or are spaced from the pedicles and that the spinal disc would need to be removed or to place an implant between the vertebrae. Conchy et al. teach (Fig. 8) that the insertion members and corrected member rod are to be used laterally in the sidewall of vertebrae spaced from and not engaging the pedicle. It would be an obvious expedient to space the insertion members from the pedicles to be placed in the sidewall or lateral wall of the vertebrae since it is a larger bony mass of tissue and has more structural support for the screw. Kapp et al. teach (Fig. 1) that a prosthesis is to be inserted into the intervertebral space that also used a bone screw and connector member that spans the vertebrae. Jackson additionally teaches that first an intervertebral disc is removed to define a space for an implant, col. 2, lines 46-48, col. 4, lines 17-20. It would have been obvious to one of ordinary skill in the art to remove disc

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material if necessary or degenerative as taught by Kapp et al. when performing the procedure of Jackson and inserting bone screws spaced from and not in the pedicle as taught by Conchy et al. and the connecting member laterally on the vertebrae such that no further damage or painful conditions continue and the degenerative area is stabilized. Regarding claim 13, the Examiner is not giving any special meaning to the term "joint" to limit the prosthesis since no structure is defined in the claim and is being read into the claim. Thus since, Kapp's device can move it is a prosthetic "joint". With respect to claim 21, it would have been an obvious expedient to use a rotatable wrench to rotate the connecting member as such only involves routine skill in the art and would give the surgeon good torque to move the rod.

Claims 14-16,39,40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson '165 in view of Conchy et al. '612 and Kapp et al. '914 as applied to claims 13,31 above, and further in view of Marnay (5314477). Jackson as modified by Conchy et al. and Kapp et al. is explained supra. However, Jackson in view of Conchy et al. and Kapp et al. fail to disclose laterally forming slots or elongate slots in the vertebrae for laterally extending keels on a bone substitute implant inserted between the vertebrae. Marnay teaches to form lateral slots in the vertebrae, col. 3, lines 7-13,17,18,48-50, col. 7, lines 37,52,53. Marnay also shows (Fig. 2) laterally-extending keels to fit in the slots prepared in the vertebrae. Marnay also illustrates (Fig. 1) the bone substitute implant maintains space between the vertebrae. It would have been obvious to one of ordinary skill in the art to use the teaching of Marnay to prepare slots for laterally-extending keels of a bone substitute implant and modify the device of Kapp

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incorporated into the method of Jackson as modified with Conchy et al. such that the vertebral engaging members that are part of the joint replacement device has a larger attachment surface area by using keels which would better stabilize the implant between the vertebrae and not be displaced.

Claims 18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson '165 in view of Conchy et al. '612 and Kapp et al. '914 as applied to claim 17 above, and further in view of Wagner et al. (6030389). Jackson in view of Conchy et al. and Kapp et al. is explained supra. However, Jackson as modified by Conchy et al. and Kapp fail to disclose the type of screws used in the surgical procedures. Wagner et al. teach that there are two types of screws used in spinal stabilization procedures, bi-cortical and uni-cortical and enable the surgeon to decide which to use based on the type of device the screws are used with, col. 1, lines 31-44. It would have been obvious to one of ordinary skill in the art to utilize either bi-cortical or uni-cortical as taught by Wagner et al. in the method of spinal repair with the spinal implant of Jackson in view of Conchy et al. and Kapp et al. such that the implantable screws and connectors remain in place and provide the proper alignment for the patient.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Boyd (5683391) teaches inserting a screw in the vertebral wall and using a rod to connect with other insertion members and rotating the rod.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738